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PATENT REQUEST : STANDARD PATENT

(We being the person(s) identified below as the Applicant(s), request the grant of a patent to the person(s) identified below as the Nominated Person(s), for an invention described in the accompanying standard complete specification.

Full application details follow:

[71/70] Applicant(s)/Nominated Person(s):

EndoVascular Technologies, Inc:

of

1360 O'Brien Drive, Menlo Park, California, 94025, United States of America

[54] Invention Title:

Endovascular graft having bifurcation and apparatus and method for deploying the same

[72] Name(s) of actual inventor(s):

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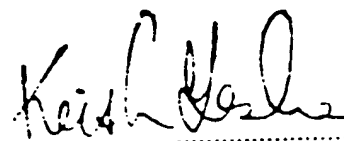
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Basic Convention Application(s) Details:

[31] Application Number	[33] Country	Code	[32] Date of Application
Nil	Nil	Nil	Nil

DATED this THIRTIETH day of JUNE 1992



a member of the firm of
DAVIES COLLISON CAVE for
and on behalf of the
applicant(s)

AUSTRALIA
PATENTS ACT 1990
NOTICE OF ENTITLEMENT

We, EndoVascular Technologies, Inc., the applicant/Nominated Person in respect of Application No. 18695/92 state the following:-

The Nominated Person is entitled to the grant of the patent because the Nominated Person derives title to the invention from the inventors by assignment.

DATED this TWENTY FOURTH day of JULY 1992

.....
a member of the firm of
DAVIES COLLISON
CAVE for and on behalf
of the applicant(s)

(DCC ref: 1507755)

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ENDOVASCULAR GRAFT HAVING BIFURCATION AND APPARATUS AND METHOD FOR
DEPLOYING THE SAME

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(56) Prior Art Documents
EP 466518
US 5047050
US 4693249

(57) Claim

1. A graft device having a bifurcation for repairing an aortic aneurysm close to or involving the aortic bifurcation having an arterial wall in a patient, said device comprising: a main tubular body and first and second tubular legs joined to said main body in a bifurcation, said main body and said legs being formed of a flexible surgically implantable material, said main body and said first and second legs having respectively first, second and third openings therein in communication with each other, expandable anchor means secured to said main body adjacent the first opening and additional expandable anchor means secured to said first leg adjacent the second opening.

8. An endovascular graft suitable for residence in the vasculature of a patient for repairing an aortic aneurysm proximate the aortic bifurcation, comprising:

a. support means having a bifurcation with a main body and first and second tubular bodies for reinforcing the aortic bifurcation proximate the aneurysm to prevent rupture, said support means in fluid communication with the vasculature;

b. a plurality of expandable anchoring means for attaching said support means to the vasculature and for forming a substantially fluid-tight seal with the vasculature; and

c. marker means for positioning said support means in the aortic bifurcation relative to the aneurysm so that said anchoring means may be affixed to healthy vasculature tissue on either side of said aneurysm.

AUSTRALIA
PATENTS ACT 1990
COMPLETE SPECIFICATION

NAME OF APPLICANT(S):

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INVENTION TITLE:

Endovascular graft having bifurcation and apparatus and method for deploying the same

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

TECHNICAL FIELD

This invention relates to an endovascular graft having bifurcation and an apparatus and a method for deploying the same.

BACKGROUND OF THE INVENTION

5 In U.S. Patent No. 4,617,932 there is disclosed a bifurcated graft which has two legs with one leg being longer than the other leg. There is also disclosed a device and a method for inserting the graft into an artery. However, there is a need for an improved endovascular bifurcated graft and an apparatus and a method for deploying the same.

10 In general, it is an object of the present invention to provide an endovascular graft having bifurcation and an apparatus and a method for deploying the same which makes it possible to secure the graft firmly in place traversing the aortic bifurcation with an apparatus and method which facilitates rapid deployment and placement of the same.

Another object of the invention is to provide a graft of the above character which has a body portion that can be firmly fixed in place in the aorta and has legs which can be firmly
15 fixed in place in the iliac arteries.

Another object of the invention is to provide a method of the above character which is relatively simple and error free.

According to the present invention there is provided a graft device having a bifurcation for repairing an aortic aneurysm close to or involving the aortic bifurcation having an arterial
20 wall in a patient, said device comprising: a main tubular body and first and second tubular legs joined to said main body in a bifurcation, said main body and said legs being formed of a flexible surgically implantable material, said main body and said first and second legs having respectively first, second and third openings therein in communication with each other, expandable anchor means secured to said main body adjacent the first opening and additional
25 expandable anchor means secured to said first leg adjacent the second opening.

The invention also provides an endovascular graft suitable for residence in the vasculature of a patient for repairing an aortic aneurysm proximate the aortic bifurcation, comprising:

- a. support means having a bifurcation with a main body and first and second
30 tubular bodies for reinforcing the aortic bifurcation proximate the aneurysm to prevent rupture, said support means in fluid communication with the vasculature;
- b. a plurality of expandable anchoring means for attaching said support means to the vasculature and for forming a substantially fluid-tight seal with the vasculature; and

c. marker means for positioning said support means in the aortic bifurcation relative to the aneurysm so that said anchoring means may be affixed to healthy vasculature tissue on either side of said aneurysm.

The invention also provides an endovascular graft for attachment in a patient's
5 vasculature for repairing an aortic aneurysm proximate to the aortic bifurcation, comprising:

- a. a main tubular body having a proximal end;
- b. first and second tubular members each having proximal ends and each joined to and in fluid communication with said main tubular body;
- c. expandable anchoring means for anchoring said main tubular body at its
10 proximal end to the vasculature;

d. means for anchoring each of said first and second tubular members at their respective distal ends to the vasculature, said anchoring means providing a substantially fluid-tight seal between the vasculature and the graft so that there is fluid communication between the vasculature and said main tubular body and said first and second tubular members.

15 The invention also provides an endovascular graft for attachment in a patient's vasculature for repairing an aortic aneurysm proximate to the aortic bifurcation, comprising:

- a. a main tubular body having a proximal end and extending proximally to the aortic bifurcation;
- b. first and second tubular members each having proximal ends and each joined
20 to and in fluid communication with said main tubular body, said first tubular member extending distally into the first iliac artery and said second tubular member extending distally into the second iliac artery;

c. means for anchoring said main tubular body at its proximal end to the vasculature;

25 d. means for anchoring each of said first and second tubular members at their respective distal ends to the vasculature, said anchoring means providing a substantially fluid-tight seal between the vasculature and the graft so that there is fluid communication between the vasculature and said main tubular body and said first and second tubular members.

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The invention also provides in a method for deploying a graft having bifurcation with a main body and first and second legs for deployment across an aortic bifurcation of a patient to repair an aneurysm close to or involving the aortic bifurcation and the associated first and second iliac arteries, folding the second leg of the graft so it lies substantially parallel to the main body of the graft to provide a folded-over second leg, introducing the graft with the folded-over second leg through the first iliac artery until the graft is disposed proximal of the bifurcation, securing the proximal extremity of the graft with the first leg of the graft being disposed in the first iliac artery, pulling down the folded-over second leg into the second iliac artery, securing the distal extremity of the first leg in the first iliac artery and thereafter securing the second leg of the graft in the second iliac artery.

The invention also provides a method for positioning an endovascular graft suitable for residence in the vasculature of a patient for repairing an aortic aneurysm proximate the aortic bifurcation, the graft having a main tubular body and first and second tubular members joined thereto, the method comprising:

- 15 inserting the graft into the femoral artery;
- locating the graft adjacent the aneurysm near the aortic bifurcation;
- adjusting the position of the graft relative to the aortic aneurysm;
- anchoring the proximal end of the main tubular member in healthy tissue on one side of the aortic aneurysm;
- 20 positioning the first and second tubular members in respective first and second iliac arteries;
- anchoring the distal ends of the first and second tubular members to the respective first and second iliac arteries; and
- providing a substantially fluid-tight seal at each anchor point so that the graft is in fluid communication with the vasculature and iliac arteries.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a plan view of the apparatus for deploying an endovascular graft having a bifurcation of the present invention in which the graft is disposed within the capsule ready for deployment.

FIGURE 2 is a cross-sectional view taken along the line 2-2 of Figure 1.

FIGURE 3 is an enlarged cross-sectional view showing the sliding seal assembly utilized in the device shown in Figure 1.

FIGURE 4 is an enlarged perspective view of a graft having a bifurcation incorporating the present invention.

FIGURE 5 is an enlarged schematic view of the capsule showing the manner in which the graft having bifurcation is stored therein for deployment.

FIGURE 6 is an elevational view partially in cross section of a minor deployment device utilized as a part of the apparatus for deploying the graft of the present invention.

FIGURE 7 is an elevational view partially in cross section of the balloon dilatation catheter utilized in the minor deployment device shown in Figure 6.

FIGURE 8 is a perspective view of the hook assembly forming a part of the minor deployment device shown in Figure 6 to be utilized with the graft shown in Figure 4.

FIGURES 9-19 are diagrams showing the method and apparatus utilized in deploying the graft of the present invention.

DETAILED DESCRIPTION

In general, the present invention provides a graft having a bifurcation for repairing an aneurysm in the aorta

extending to or beyond the aortic bifurcation in a patient comprising a main tubular body and first and second tubular legs joined to said main body in a bifurcation. The main body and the legs are formed of a flexible surgically implantable material. The main body and the first and second legs each have an opening therein in communication with the other openings. Expandable spring attachment means is secured to the main body adjacent the opening in the main body. Additional spring attachment means is secured to the first leg adjacent the opening in that leg. The major deployment device comprises a capsule catheter and a balloon catheter. The capsule catheter comprises a flexible elongate tubular member having proximal and distal extremities. A capsule is mounted on the distal extremity of the flexible elongate tubular member and has an open end. A graft is disposed within the capsule. The balloon catheter comprises a flexible elongate tubular member having proximal and distal extremities. A balloon is secured to the distal extremity of the flexible elongate tubular member of the balloon catheter. The flexible elongate tubular member of the balloon catheter extends through the graft and through the capsule in which the graft is disposed and through the flexible elongated tubular member of the capsule catheter. Retention means is carried by the flexible elongate tubular member of the balloon catheter and engages the graft. A control mechanism is provided and has a handle portion adapted to be grasped by a human hand and has first and second parts movable relative to each other. Means is provided for securing the flexible elongate tubular member of the capsule catheter to the first part. The flexible elongate tubular member of the balloon catheter extends through the first part and through the control mechanism. Means is carried by the control mechanism for causing movement of the first part with respect to the second part to thereby cause the capsule to be withdrawn from over the graft and permitting the retention means to retain the graft in position so that it is ejected from the capsule as the first part is moved relative to the second part.

The method for deploying a graft having bifurcation with a main body and first and second legs for deployment

across the aortic bifurcation and into the first and second
iliac arteries of a patient to repair an aneurysm therein
comprising folding one of the legs of the graft so it lies
substantially parallel to the main body of the graft,
5 introducing the graft through the femoral artery until the
distal portion of the graft is disposed proximal of the aortic
aneurysm, securing the proximal extremity of the graft with
the other leg of the graft being disposed in the first iliac
artery, pulling down the folded over leg into the second iliac
10 artery securing the distal extremity of the first leg of the
graft in the first iliac artery and thereafter securing the
second leg of the graft in the second iliac artery.

The apparatus for deploying a graft 20 having a
bifurcation of the present invention consists of a major
15 deployment device 21 which is shown particularly in Figure 1
and a minor deployment device 22 which is shown in Figure 6.
The major deployment device 21 incorporates a capsule catheter
26 which is very similar to a capsule catheter disclosed in
~~Australian Patent NO. 649051.~~
~~Co-pending Application Serial No. 07,553,530 filed July 13,~~
20 ~~1990.~~ As disclosed therein, the capsule catheter 26 is
provided with a flexible elongated tubular member 27 formed
of a plastic which is loaded with a radiopaque material so that
it will be visible under X-rays. An inner liner 28 of
lubricous material is disposed within the tubular member 27.
25 A flexible capsule 31 is secured to the distal extremity of
the tubular member 27. The capsule can have a length ranging
from 10-40 centimeters and a diameter ranging from 6-9
millimeters.

A control mechanism 36 is secured to the proximal
30 extremity of the tubular member 27. The control mechanism 36
is provided with a multipart housing 37, a portion of which
serves as a handle adapted to be engaged by the adult human
hand. The housing 37 is formed in two parts 37a and 37b of
a suitable material such as plastic. The part 37a serves as
35 a cylindrical pinion housing which has a longitudinally
extending bore 39 formed therein opening through one end
thereof. A smaller bore 41 is provided in the pinion housing
37a and extends axially thereof and opens into the bore 39.
The part 37b is secured to the part 37a by suitable means such

as ultrasonic bonding. The part 37b serves as a rack housing. A generally cylindrical rack member 42 is slideably mounted in the bore 39. Means is provided for causing relative movement between the rack member 42 and the pinion housing 37a and consists of a rack and pinion assembly 43. The rack and pinion assembly 43 consists of a rack 44 which is mounted in a flat 46 provided on the rack member 42. The rack 44 is engaged by a pinion 47 mounted on a shaft 48. The shaft 48 extends through the pinion housing 37a and is provided with an enlargement 48a on one end. A knob 49 is mounted on the other end of the shaft 48 and is provided for rotating the shaft 48 by fingers of one hand of the operator. The other hand of the operator holds the control mechanism 36.

A detent assembly 51 is provided for permitting step-by-step rotation of the knob 49 in one direction but preventing rotation in an opposite direction. The detent assembly 51 consists of a plastic cylindrical housing 52 mounted in the wall of part 37a and has a plunger 53 slideably mounted therein which is yieldably urged in a direction towards the knob 49 by a coil spring 54. The plunger 53 serves as a detent which is adapted to engage the circumferentially spaced notches 56 provided in the knob 49. The notches 56 are shaped so that the knob 49 can only be rotated in one direction and not in the other direction.

The distal extremity of the rack housing 37b is provided with a bore 61 (see Figure 3) which opens through the distal extremity of the same. A smaller bore 62 is provided within the rack member 42 and extends axially of the bore 61 and opens into the bore 61 and also opens through the proximal extremity of the rack member 42. A sliding seal housing 63 is provided within the bore 61 and is secured therein by suitable means such as an adhesive. The housing 63 is provided with a bore 64 which opens through the proximal extremity of the housing 63 and a smaller bore 66 extending axially of the bore 64 and opening into the bore 64 and opening through the distal extremity of the housing 63. The sliding seal housing 63 is provided with an annular recess 67 on its distal extremity which is adapted to receive the proximal extremity

of the flexible elongate member 27 and is bonded thereto by suitable means such as an adhesive.

The major deployment device 21 also includes a balloon catheter assembly 71 of the type disclosed in EP-A-0,466,518 and which includes a flexible elongate tubular member in the form of a balloon catheter shaft 72 having a single lumen therein and formed of a suitable material such as irradiated polyethylene tubing. A separate balloon 74 is secured to the distal extremity of the balloon catheter shaft 72 and is formed of a suitable material such as polyethylene. The balloon catheter shaft 72 can have a suitable outside diameter such as .050" (1.27 mm) and extend into a metal hypo tube 76 formed of a suitable material such as stainless steel having a suitable outside diameter, for example .062" (1.57 mm). The metal tube 76 extends into the inner liner 28 and extends into the bore 66 of the sliding seal housing 63 and into the bore 64 where it engages a pair of the spaced-apart cylindrical members 77 and 78 formed of a suitable material such as polycarbonate and a pair of spaced-apart silicone O-rings 79 and 81, all of which are disposed within the bore 64 to form sliding seals. These sliding seals formed by the cylindrical members 77 and 78 in conjunction with the O-rings 79 and 81 serve to prevent body fluids from coming into contact with operating parts of the control mechanism 36 as for example, the rack pinion assembly 43. The stainless steel hypo tube 76 extends rearwardly towards the proximal extremity through the passage 62 of the rack member 42 and into the bore 41 of the pinion housing 37a. A collet 82 is provided on the proximal extremity of the pinion housing 37a. Means is provided for permitting free rotational movement of the hypo tube 76 in a fixed longitudinal position and consists of a collet housing 83 having a threaded split cylindrical protrusion 83a with a collet cover 84 threaded thereon. The collet cover 84 has a hole 85 therein through which the hypo tube 76 passes. The collet housing 83 is rotatably mounted by an isolation ball bearing assembly 86 on a base 87 provided on the housing part 37a. When the collet cover 84 is rotated in one direction, the collet housing protrusion 83a is permitted to move to its normally open position to permit the

collet 82 to open allowing the tube 76 to pass therethrough. When the collet cover 84 is rotated in an opposite direction it will close the housing protrusion 83a and lock the collet 82 onto the tube 76. A Luer-type fitting 88 is mounted on the proximal extremity of the hypo tube 76.

A pusher wire 89 of a suitable material such as stainless steel and of a suitable diameter as, for example, .018" (0.46mm) is disposed within the balloon catheter shaft 72 and extends the length thereof. The proximal extremity 89a of the pusher wire 89 is secured in a fixed position to the luer fitting 88 in a suitable manner such as by embedding in the wall of the fitting 88 as shown in Figure 1. The pusher wire 89 extends through the lumen of the balloon catheter shaft 72 into the balloon 74 where it is fastened in a fixed position in the distal extremity of the balloon 74. A flexible, pre-shaped spring-like guide wire 91 is secured to the distal extremity of the balloon 74 by use of a plug 92 which also receives the distal extremity of the pusher wire 89.

Means is provided as a part of the control mechanism 36 for supplying liquids for injection into the capsule 31 and consists of a fitting 96 (see Figure 3) which is mounted in the rack member 42 and which is provided with a bore 97 in communication with the bore 66. A flexible tube 99 is connected to the fitting 96 and is provided with a Luer-type fitting 101 having a stop cock 102 therein. The rack housing or cover 37b is provided with a slot 103 through which the tube 99 extends and can move longitudinally during rectilinear movement of the rack member 42.

A stabilization button 106 is mounted on the balloon catheter shaft 72 in a fixed position spaced a predetermined distance from the proximal extremity of the balloon 74 as for example, a distance of 5-10 centimeters. A pair of spaced-apart radiopaque markers 107 in the form of platinum bands are provided on the balloon catheter shaft 72 within the balloon 74.

The endovascular graft 20 having a bifurcation is shown in Figure 4. The graft 20 has many characteristics which are similar to the expandable intraluminal vascular graft disclosed in EP-A-0,466,518. However, graft 20 differs

significantly from the grant disclosed therein in that it is provided with a bifurcation as hereinafter described. The graft 20 is an expandable intraluminal vascular graft which is provided with a main deformable cylindrical body 112 having an open end 113. The body 112 is provided with a bifurcation or crotch 114 at the other end which opens into first and second legs 116 and 117, having open ends 118 and 119 generally opposite the open end 113. Continuous walls form the body 112 and the legs 116 and 117 and are woven of surgically implantable material such as Dacron-type fiber. One material found to be particularly satisfactory is a USCI DeBakey soft woven Dacron vascular prosthesis. The main body 112 can have a length ranging from 5 to 30 centimeters with each of the legs having a length ranging from 2 to 15 centimeters. The body 112 can have a maximum expandable diameter ranging from 12 to 30 millimeters whereas the legs 116 and 117 can have maximum diameters ranging from 6 to 12 millimeters.

Radiopaque markers 121 are provided on the main body 112 and also on the legs 116 and 117 and can be formed of a suitable material such as lengths of platinum wire secured to the fabric of the graft by suitable means such as Dacron sutures.

Expandable spring attachment means 126 is secured to the expandable main body adjacent the opening 113. Also expandable spring attachment means 127 is secured to the first leg 116 adjacent the opening 118. These expandable spring attachment means 126 and 127 serve as anchoring means for securing the graft 20 to vessel wall in which the graft 20 is disposed. The expandable spring attachment means 126 is constructed in a manner similar to that described in EP-A-0,466,518 and serves to yieldably urge the opening 113 in the main body 112 from an initial compressed or collapsed position to a subsequent expanded position. Similarly, the expandable spring attachment means 127 serves to yieldably urge the open end 118 from an initial compressed or collapsed position to a subsequent expanded position. As explained in EP-A-0,466,518, the expandable spring attachment means 126 and 127 are formed of a plurality of vees 131 with the apices 132 being formed with helical coil springs 133 to yieldably urge

the legs 134 and 136 of each of the vees 131 outwardly in directions in the planes in which the vees lie. As disclosed in EP-A-0,466,518, the apices 133 lie in three longitudinally spaced-apart parallel planes extending transversely of the axis of the expandable spring attachment means in which the first plane is disposed internally of the open end and the second plane lies in a position which is external of but in close proximity to the open end and the third plane is spaced a substantial distance beyond the open end.

Hook-like elements 141 are provided at the apices 132 which are disposed beyond the open end 113 for the attachment means 126 and the open end 118 for the attachment means 127. The hook-like elements 141 are bonded to the legs 136 of the vees 131 by suitable means such as welding. The hook-like elements 141 have hooks 142 which are of a length which is sufficient to penetrate into the vessel wall and slightly beyond the vessel wall in which the graft is to be placed. The expandable spring attachment means 126 and 127 are secured to the graft by Dacron polyester suture material 144 as shown particularly in Figure 4.

A pull line 146 is secured to the leg 117 in a region which is closely approximate the end of the leg 117 at the opening 119. The pull line can be formed of a suitable material such as Nylon having a diameter from .005"-0.010" (0.13-0.25 mm). The pull line 146 is continuous and extends through small holes 147 provided in the material forming the graft 20. The pull line 146 which is doubled over onto itself and has a doubled-over length of approximately 40-60 centimeters with the ends of the pull line 146 being tied together in a knot 148. A lead tube 151 with a lumen 152 is positioned over the pull line 146 so it is adjacent the leg 117. The lead tube 151 is necked down at 153 by suitable means such as by heat in a region distal of the knot 148 (see Figure 4) so that the lead tube 151 is retained on the pull line 146. A cutout 154 is provided in the lead tube 151 proximal of the knot 148.

The balloon catheter assembly 71 is disposed within the capsule 31 in a manner also shown in Figure 5 in which the balloon tube or shaft 72 extends coaxially of the main body

of the graft 112 coaxially of the first leg 116. The stabilization button 106 is preferably disposed within the graft in a position which is just proximal of the bifurcation or crotch 114. By positioning the pusher button 106 where
5 shown in Figure 5, it is near to the major portion of the material forming the graft 20 which is folded up within the capsule 31. This is desirable because the mass of material provided in that region of the capsule facilitates pushing the graft 20 out of the capsule as hereinafter described.

10 The minor deployment device 22 as particularly shown in Figure 6 consists of a capsule catheter 161, a balloon catheter 162 and a separate expandable spring attachment means 163. The separate balloon catheter 162 is shown in greater
15 detail in Figure 7 and the separate spring attachment means 163 is shown in Figure 8. The capsule catheter 161 consists of a flexible tubular member 166 formed of a suitable material such as polyethylene having an inside diameter ranging from .050 to .080" (1.27 mm to 2.03 mm) and an outside diameter ranging from .075 to 0.100" (1.91 to 2.54 mm). The tubular
20 member 166 can have a suitable length as for example, 15-25 centimeters. The tubular member 166 has a lumen 167 extending the length thereof and has proximal and distal extremities 168 and 169. A conventional Tuohy Borst adapter 171 is mounted on the proximal extremity 168. A small capsule 172 formed of
25 suitable material such as stainless steel is mounted on the distal extremity 169 of the tubular member 166. It can be of a suitable size, as for example a length of 10 to 30 millimeters and an inside diameter of 4 to 6 millimeters with a wall thickness ranging from .006 to .015" (0.150 to 0.381
30 mm). The capsule 172 is provided with an open end 173 through which the separate expandable spring attachment means 163 is adapted to be inserted.

The balloon catheter 162 as shown in Figure 7 consists of a flexible elongated tubular member 176 formed of
35 a suitable material such as polyethylene and which serves as the balloon shaft and is provided with an outside diameter ranging from 0.04 to 0.060" (1.02 to 0.15 mm) and an inside diameter ranging from 0.015 to 0.030" (0.38 to 0.76 mm). An expandable balloon 177 is formed integral with the flexible

elongate tubular member 176 near the distal extremity thereof. The balloon 177 is formed of the same polyethylene material as the tubular member 176 and can have a diameter ranging from 6 to 12 millimeters and a length ranging from 1 to 2 centimeters. A wye adapter 179 is mounted on the proximal extremity 181 of the flexible elongated tubular member 176. A Tuohy Borst adapter 182 is mounted on the main arm 183 of the wye adapter 179. A stop cock 184 is mounted on the side arm 186 of the wye adapter 179.

10 An additional elongate flexible tubular member 188 of a suitable material such as polyethylene is provided and extends from the Tuohy Borst adapter 182 through the lumen 189 provided in the tubular member 176 and through the balloon 177 where the distal extremity of the elongate flexible tubular
15 of the member 188 is bonded to the distal extremity of the tubular member 176 to provide an airtight seal for the balloon 177. The tubular member 188 is provided with a lumen 191 extending the length thereof as adapted to receive a guide wire
: 196 of a suitable size as for example, one having a diameter
: 20 of .018" so that the guide wire 196 can extend through the
: tubular member 176 and through the balloon 177 and extend
: beyond the distal extremity of the tubular member 176. The
: guide wire 196 is of a conventional type and is utilized for
: guiding the balloon catheter as hereinafter described. A pair
25 of spaced-apart radiopaque markers of a suitable material such
: as gold bands 198 are provided on the tubular member 188 within
: the balloon 177.

 The coaxial annular space between the exterior of the tubular member 188 and the interior of the tubular member
30 176 serves as an annular balloon inflation passage and is in communication with the side arm 186 so that the inflation and deflation of the balloon can be controlled by the stop cock
: 184.

 The expandable spring attachment means 163 shown in
35 Figure 8 has a construction very similar to the expandable spring attachment means 126 and 127 hereinbefore described. The expandable spring attachment means 163 is provided with a plurality of vees 201 having apices 202 formed by coil springs 203 which have legs 204 and 206 expandable and

contractible within the plane of the vee. The vees 201 are configured in such a manner so that the apices 202 lie in only two spaced-apart parallel planes perpendicular to the longitudinal axis of the expandable spring attachment means, rather than the three planes disclosed for expandable spring attachment means 126 and 127. Hook-like elements 207 are bonded to the legs or struts 204 or 206. The hook-like elements 207 are provided with hooks 208 which face outwardly of the expandable spring attachment means and in a direction towards the other end of the spring attachment means. Additional hook-like elements 209 are provided on the other end of the spring attachment means 163 by bonding the same by suitable means such as welding to the struts 204 and are provided with hooks 211 which face outwardly and extend in an opposite direction to the hooks 208, toward the other end of the spring attachment means. In this way it can be seen that the hooks 208 and 211 face in opposite directions, hooks 208 being angled slightly distally and hooks 211 being angled slightly proximally, and serve to prevent distal and proximal migration of the graft leg 117 to which the expandable attachment means 163 is attached as hereinafter described.

The expandable spring attachment means 163 is adapted to be compressed and mounted within the capsule 172 as shown particularly in Figure 6. Means is provided for pushing the expandable spring attachment means 163 out of the open end 173 of the capsule 172 and consists of a stabilization button 216 which is formed on the balloon shaft or flexible elongate tubular member 176. The pusher member 216 can be formed in a suitable manner such as by forming a ring of longitudinally compressed polyethylene on the shaft 176.

Operation and use of the apparatus hereinbefore described for performing the method of the present invention for deploying an endovascular graft having bifurcation may now be briefly described as follows.

In conjunction with the diagrams which are set forth in Figures 9-19, let it be assumed that it is desired to repair an aneurysm in the abdominal aorta 222 close to or involving the aortic bifurcation 221 and possibly involving the left and right iliac arteries 223 and 224 in a human patient. In this

example, the left iliac artery 223 is referred to as the first iliac artery, and the right iliac artery 224 is referred to as the second iliac artery. Graft legs 116 and 117 are identified similarly. Initially the patient is prepared with either general, regional, or local anesthesia. A cut-down is performed in the left femoral artery as indicated by the opening 226 in the first leg 223. Similarly, a cut-down or percutaneous access is performed in the right femoral artery as indicated by the opening 227 in the second leg 224. A guide wire 231 of a conventional type, as for example a guide wire having a diameter of .038" (0.97 mm), is introduced through the opening 226 in the left femoral artery 223 and then is passed over the aortic bifurcation 221 and down through the right artery 224 and out through the opening 227 in the right femoral artery. This procedure is accomplished in a conventional manner under fluoroscopy as shown in Figure 9.

Thereafter as shown in Figure 10 the lead tube 151 which is extending out of the distal extremity of the capsule 31 is threaded over the guide wire 231 extending out of the hole 226 in the first artery 223 and thence into the left cut-down or hole 226 and over the guide wire 231 in the left artery, over the guide wire 231 in the aortic bifurcation 221 and then down the second artery 224 through the right cut-down 227 so that the distal extremity of the lead tube 151 extends for a substantial distance out of the cut-down 227. During the time that the lead tube 151 is being advanced, the distal extremity of the guide wire 231 is caused to pass through the cut-out 154 so that the distal extremity of the guide wire 231 is accessible and can be held steady while the lead tube 151 is advanced over it.

Thereafter, the guide wire 231 can be pulled out by grasping the proximal extremity of the guide wire 231 adjacent the cut-out 154 in the lead tube 151 and pulling out the guide wire 231 while holding the distal extremity of the lead tube 151 so as to prevent the lead tube 151 from being pulled back into the cut-down 227. The distal extremity of the lead tube 151 is then clamped with a hemostat 236 as shown in Figure 11 to be sure that the lead tube 151 is not pulled back into the cut-down 227 during future steps in the method of the present

invention. The major deployment device 21 is then introduced into the left cut-down 226 by first passing the balloon guide wire 91 and then the balloon 74 through the left cut-down 226 followed by the capsule 31, which is advanced to the position shown in Figure 11 by pushing on the tubular member 27. During the advancement, the operator may need to place gentle traction on the lead tube 151 to facilitate advancement of the capsule 31 toward the aortic bifurcation 221. When the capsule 31 reaches the aortic bifurcation 221, it is necessary for the operator holding the lead tube 151 to permit more of the lead tube 151 to enter the cut-down 227 to permit further advancement of the capsule 31 up the aorta so that the distal spring attachment means 126 of the graft 20 within the capsule 31 can be positioned in a region which is 1-2 centimeters proximal of the proximal extremity of the aneurysm to be corrected by the graft 20 being deployed. As shown in Figure 12 the distal extremity of the capsule 31 is deployed well beyond the aortic bifurcation 221. As soon as the physician has determined that the capsule 31 is in the proper position, the physician uses one hand to hold the control mechanism 36 while at the same time using the fingers of the other hand to rotate the knob 49 and the pinion 47 to retract the rack member 42. This causes retraction of the tubular member 27 and the capsule 31 mounted thereon while the hypo tube 76 is retained in a stationary position by the collet 82 that is retained by the collet housing 83. As the capsule 31 is withdrawn, the stabilization button 106 carried by the tubular member 72 in engagement with the graft 20 as shown particularly in Figure 5 causes the graft 20 to be gradually ejected from the capsule 31 as the capsule 31 is withdrawn. Upon continued retraction of the capsule 31, the proximal expandable spring attachment means 126 will clear the capsule 31 and will spring outwardly to cause the hooks 142 carried thereby to come into engagement with the aortic vessel wall proximal to the aneurysm to be repaired as shown in Figure 12.

The physician, using one hand to hold the control mechanism 36, uses his other hand to release the collet 82 in order to unlock the tube 76 by rotating the collet cover 84 relative to the control mechanism 36. The physician

repositions the hand not holding the control mechanism 36 so as to grasp the portion of the metal hypo tube 76 extending proximally of the control mechanism 36. The hypo tube 76 is then pulled rearwardly or proximally. The balloon 74 is thereby drawn into the proximal extremity of the main body portion 112 of the graft 20 as shown in Figure 13 so that the intermediate portion of the balloon 74 is in general registration with the expandable spring attachment means 126. The balloon 74 is then inflated by supplying gas to the balloon inflation lumen by attachment of a syringe or other suitable inflation means to the Luer fitting 88. Upon inflation of the balloon 74 the hooks 142 carried by the proximal expandable spring attachment means 126 are firmly seated circumferentially in the normal aortic wall proximal to the aortic aneurysm. With the balloon 74 still inflated and firmly holding the proximal attachment means 126 against the aortic wall, the capsule 31 is then further retracted by holding tube 76 in fixed position relative to the patient with one hand and retracting the handle 36 with the other hand in order to expose the entire length of the second leg 117 as shown in Figure 13. The capsule 31 is still further retracted to clear most of the first leg 116 as shown in Figure 14. As this is being accomplished, the second leg 117 of the graft 20 is pulled down into the artery 224 by pulling on the lead tube 151 so that the entire length of the leg 117 of the graft 20 is disposed in the arterial vessel 224 and extends substantially below the bifurcation 221 and below the aneurysm which is to be repaired. Further retraction of the capsule 31 is accomplished by holding tube 76 fixed with one hand and retracting the handle 36 with the other hand until the distal expandable spring attachment means 127 carried by the first leg 116 clears the capsule 31 and springs into engagement with the wall of the arterial vessel 223. It should be appreciated that during the foregoing procedures, the balloon 74 remains inflated in the attachment means 126 to prevent any accidental dislodgement of the attachment means 126 during the removal of the capsule 31 and during the placement of the second leg 117 of the graft 20 into the artery 224 by pulling on the lead line 151.

The balloon 74 is then deflated so that it is in a collapsed position and the balloon is withdrawn from the attachment means 126 into the first leg 117 until its intermediate portion is in registration with the attachment means 127. The balloon 74 is then reinflated to expand the hooks 142 of the attachment means 127 into firm engagement with the arterial wall of the vessel 223 as shown in Figure 15.

After this has been accomplished, the balloon 74 is again deflated and is advanced up through the main body of the graft 112 and again into the attachment means 126. The balloon 74 is then reinflated as shown in Figure 16 and serves to hold the graft 20 in place while the procedures for securing the distal extremity of the second leg 117 are accomplished. It is likely in many instances that this step of again securing the proximal extremity of the graft by inflating the balloon in the attachment means 126 may be unnecessary. However to ensure that the graft 20 will not move after it has been deployed, as additional insurance, the balloon 74 can be positioned in the attachment means 126 and reinflated.

The minor deployment device 22 is next utilized. The guide wire 196 forming a part thereof is introduced through the cutdown 227 into the second artery 224 so that it extends into the second leg 117 of the graft 20 and beyond the bifurcation. The balloon catheter 162 is threaded onto or advanced over the guide wire 196. The balloon catheter 162 is disposed within the capsule catheter 161. The minor deployment device 22, with its balloon catheter 162 and capsule catheter 161, is advanced into the cutdown 227 while applying gentle traction to the lead tube 151 to keep the second leg 117 of the graft 20 taut. The balloon 177 and the capsule 172 are thus introduced into the second leg 117. The capsule 172 is positioned so that when the expandable spring attachment means 163 contained therein is deployed therefrom, the spring attachment means 163 will be at the distal extremity of the second leg 117 of the graft 20 as shown in Figure 16. The expandable spring attachment means 163 is then forced out of the capsule 172 by the physician using one hand to grasp the wye adapter 179 and hold it in a fixed position relative to the patient and using the other hand to grasp the Tuohy Borst

adapter 171 and gradually withdraw the same to retract the capsule 172 from over the expandable spring attachment means 163 which is held in the desired position by the stabilization button 216 carried by the tubular member 176. As soon as the expandable spring attachment means 163 clears the capsule 172 it will spring out with one row of hooks 208 moving into engagement with the distal extremity of the second leg 117 and with the other row of hooks 211 moving into engagement with the wall of the arterial vessel 224. Alternatively the capsule 172 is positioned so that when the expandable spring attachment means 163 contained therein is displaced therefrom, the expandable spring attachment means 163 is disposed within the second leg 117 so that both rows of hooks 208 and 211 move into engagement with the distal extremity of the leg 117 and engage the wall of the vessel 224.

In order to firmly implant the hooks 208 and 211 of the expandable spring attachment means 163, the balloon 177 in its deflated condition is brought down into the attachment means 163 so that its intermediate portion is disposed within the attachment means 163. This is accomplished by pulling on the wye adapter 179 which applies a pulling force to the tubular member 176 to pull the balloon 177 towards the distal extremity of the leg 117 of the graft 20 while at the same time withdrawing, if so desired, the capsule catheter 161 by pulling on the adapter 171 which applies a pulling force to the tubular member 166. As soon as the balloon 177 is in the proper position, the balloon 177 is inflated by suitable inflation means as, for example, a syringe attached to the stop cock fitting 184 and inflating the balloon 177 to the desired pressure to force the hooks 208 and 211 firmly into the distal extremity of the leg 117 of the graft 20 and the arterial vessel 224.

After the inflation of the balloon 177 has been accomplished, the balloon 177 can be deflated by removing the syringe and opening the stop cock 184. The balloon catheter 162 and the capsule catheter 161 then can be removed through the cutdown 227 so that all that remains is the lead tube 151 extending through the cutdown 227. The lead tube 151 is cut distal to the knot 148 in the vicinity of the necked down

section 153 and the lead tube 151 is pulled off of the pull line 146. One end of the Nylon pull line 146 is then grasped to pull out the Nylon pull line 146 by having the free end travel up into the cutdown 227 and pass through the distal extremity of the leg 117 of the graft 20. It is then removed in its entirety through the cutdown 227. The right cutdown 227 is then repaired. Following that, the balloon 74 is deflated. The hypo tube 76 is retracted relative to the control mechanism 36 to move the balloon into engagement with the capsule 31. The collet 82 is then locked onto the hypo tube 76 by turning the knob 84 relative to the control mechanism 36. The control mechanism 36 is then withdrawn to remove the capsule catheter 27, the balloon catheter shaft 72, and the balloon 74 through the cutdown 226. The left cutdown 226 is then repaired. This completes the steps for deployment of the graft 20 across an aortic bifurcation to repair an aneurysm. The patient can then be brought out of general anesthesia if employed.

It should be appreciated that the graft having bifurcation can have legs of various lengths depending upon the type of aneurysm which is to be repaired. For example, one leg can be longer than the other. The legs can both be short in cases in which the aneurysm has a short distal aortic neck and does not include the iliac arteries. They would be longer in aneurysms which involve the iliac arteries as well. It is generally desirable that the graft extend at least one centimeter beyond the most distal portion of the most distal aneurysm in the vessels.

From the foregoing it can be seen that there has been provided a graft having a bifurcation in which the main body of the graft as well as the legs are firmly attached in the arterial vessels so that they accidentally cannot become dislodged from the location in which they are fixed in the arterial walls. The method which is utilized for deploying the graft with legs is relatively simple and can be accomplished within a relatively short period of time. The major and minor deployment devices which are utilized in the procedure are constructed in such a manner that they are easy to utilize with a minimum of training. The use of a folded-

over second leg of the graft in the capsule makes it unnecessary to move the main body of the graft as high in the aorta as would be otherwise necessary in order to permit the second leg of the graft to clear the aortic bifurcation to thereby permit the second leg to be placed in the second iliac artery. Thus, the risk incurred by moving the graft and its capsule and any associated debris past the renal arteries located well above the aortic bifurcation is greatly reduced thereby reducing the chance of occluding the renal arteries and causing embolization to the renal arteries.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A graft device having a bifurcation for repairing an aortic aneurysm close to or involving the aortic bifurcation having an arterial wall in a patient, said device comprising: a main tubular body and first and second tubular legs joined to said main body in a bifurcation, said main body and said legs being formed of a flexible surgically implantable material, said main body and said first and second legs having respectively first, second and third openings therein in communication with each other, expandable anchor means secured to said main body adjacent the first opening and additional expandable anchor means secured to said first leg adjacent the second opening.
2. A graft device as claimed in Claim 1 wherein said expandable anchor means and said additional expandable anchor means are in the form of a spring attachment means, each having hook-like elements disposed outwardly therefrom adapted to come into engagement with the arterial wall of the patient.
3. A graft device as claimed in Claims 1 or 2 further including a lead line removably connected to said second leg.
4. A graft device as claimed in Claim 3 wherein said lead line includes a single line which is looped through said material forming said second leg and a knot formed in said pull line remote from said leg.
5. A graft device as claimed in Claim 4 further including a flexible tubular member extending over said pull line into a region in close proximity to said second leg, means carried by said tubular member engaging said knot to prevent said tubular member from accidentally being removed from said pull line, said flexible tubular member having an aperture therein.
6. A graft device as in any one of the preceding claims, wherein said main body includes a plurality of

longitudinally spaced apart radiopaque marker means mounted thereon.

7. A graft device as in any one of the preceding claims, wherein a plurality of
longitudinally spaced apart radiopaque markers are carried by each of said first and second
5 tubular legs.

8. An endovascular graft suitable for residence in the vasculature of a patient for repairing
an aortic aneurysm proximate the aortic bifurcation, comprising:

a. support means having a bifurcation with a main body and first and second
10 tubular bodies for reinforcing the aortic bifurcation proximate the aneurysm to prevent rupture,
said support means in fluid communication with the vasculature;

b. a plurality of expandable anchoring means for attaching said support means to
the vasculature and for forming a substantially fluid-tight seal with the vasculature; and

c. marker means for positioning said support means in the aortic bifurcation
15 relative to the aneurysm so that said anchoring means may be affixed to healthy vasculature
tissue on either side of said aneurysm.

9. The endovascular graft of claim 8 wherein said marker means comprise a plurality of
aligned, spaced apart radiopaque markers attached to said support means so that the graft can
20 be properly located relative to the aneurysm and to allow correction of any twisting of said
support means.

10. An endovascular graft for attachment in a patient's vasculature for repairing an aortic
aneurysm proximate to the aortic bifurcation, comprising:

25 a. a main tubular body having a proximal end;

b. first and second tubular members each having proximal ends and each joined
to and in fluid communication with said main tubular body;

c. expandable anchoring means for anchoring said main tubular body at its
proximal end to the vasculature;

30 d. means for anchoring each of said first and second tubular members at their
respective distal ends to the vasculature, said anchoring means providing a substantially fluid-

tight seal between the vasculature and the graft so that there is fluid communication between the vasculature and said main tubular body and said first and second tubular members.

11. The endovascular graft of claim 10 wherein each of said anchoring means includes a
5 self-expanding spring means having a plurality of hooks which forcibly engage the patient's vasculature when said spring means self-expands.

12. The endovascular graft of claim 11 wherein said spring means has a low-profile
10 collapsed diameter permitting free movement in the vasculature and, after it self-expands, an expanded diameter that is substantially the same as or larger than the inside diameter of the patient's vasculature thereby creating a substantially fluid-tight seal.

:
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:
13. The endovascular graft of any one of claims 10 through 12 wherein said first and second tubular members are of substantially the same length.

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14. An endovascular graft for attachment in a patient's vasculature for repairing an aortic aneurysm proximate to the aortic bifurcation, comprising:

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:

a. a main tubular body having a proximal end and extending proximally to the aortic bifurcation;

b. first and second tubular members each having proximal ends and each joined to and in fluid communication with said main tubular body, said first tubular member extending distally into the first iliac artery and said second tubular member extending distally into the second iliac artery;

c. means for anchoring said main tubular body at its proximal end to the vasculature;

d. means for anchoring each of said first and second tubular members at their respective distal ends to the vasculature, said anchoring means providing a substantially fluid-tight seal between the vasculature and the graft so that there is fluid communication between the vasculature and said main tubular body and said first and second tubular members.

15. ~~26~~. In a method for deploying a graft having bifurcation with a main body and first and second legs for deployment across an aortic bifurcation of a patient to repair an aneurysm close to or involving the aortic bifurcation and the associated first and second iliac arteries, folding the second leg of the graft so it lies substantially parallel to the main body of the graft to provide a folded-over second leg, introducing the graft with the folded-over second leg through the first iliac artery until the graft is disposed proximal of the bifurcation, securing the proximal extremity of the graft with the first leg of the graft being disposed in the first iliac artery, pulling down the folded-over second leg into the second iliac artery, securing the distal extremity of the first leg in the first iliac artery and thereafter securing the second leg of the graft in the second iliac artery.

16. ~~27~~ ¹⁵. A method as in Claim ~~26~~ ¹⁵ wherein said folded-over leg is provided with a lead tube, the steps of using the lead tube to pull the folded-over second leg into the second iliac artery.

17. ~~20~~ A method as in Claim ~~17~~¹⁶ wherein the graft is provided with an opening in the main body and an opening in each of the legs together with expandable spring attachment means secured to the graft in the vicinity of the opening in the main body and additional expandable spring attachment means secured to the first leg of the graft adjacent the opening of the leg, together with a capsule catheter having a flexible elongate tubular member with proximal and distal extremities and with a capsule mounted on the distal extremity and having an open end, together with a balloon catheter having an inflatable balloon, and a deployment device with a supplemental expandable spring attachment disposed therein, said graft being disposed in said capsule so that the first named and additional expandable spring attachment means are disposed within the capsule, the steps of introducing the capsule into the arterial vessel of the patient so that the distal extremity of the capsule is disposed proximal to the aortic bifurcation and proximal of the proximal extremity of the aneurysm, withdrawing the capsule while retaining the graft therein stationary to cause the expandable spring attachment means in the vicinity of the opening in the main body to be ejected from the capsule to permit the expandable spring attachment means to expand, retracting the balloon catheter so that the balloon is disposed in the first named expandable spring attachment means, inflating the balloon to urge the first named expandable spring attachment means into engagement with the wall of the aorta, further withdrawing the capsule so that the folded over second leg clears the capsule, pulling down the folded-over second leg into the second iliac artery, still further withdrawing the capsule until the additional spring attachment means carried by the first leg of the graft clears the capsule and is permitted to expand, deflating the balloon of the balloon catheter, bringing the deflated balloon into the additional expandable spring attachment means, expanding the balloon to urge the additional expandable spring attachment means into engagement with the wall of the first iliac artery, using a deployment device to introduce supplemental expandable spring attachment means into the second iliac artery and into the second leg of the graft, urging the supplemental expandable

spring attachment means out of the deployment device and
permitting the supplemental expandable spring attachment means
to expand into engagement with the graft and into the wall of
the second iliac artery and removing the capsule catheter and
5 the balloon catheter.

18. ~~22~~ A method as in Claim ~~20~~¹⁷ together with a:
additional balloon catheter, and including the steps of:
advancing the additional balloon catheter into the supplemental
10 expandable spring attachment means, expanding the balloon into
engagement with the supplemental spring attachment means to
urge the supplemental spring attachment means into engagement
with the second leg of the graft and the wall of the second
iliac artery, removing the additional balloon catheter and
15 removing the lead tube.

19. ~~23~~ A method for positioning an endovascular graft
suitable for residence in the vasculature of a patient for
repairing an aortic aneurysm proximate the aortic bifurcation,
20 the graft having a main tubular body and first and second
tubular members joined thereto, the method comprising:
inserting the graft into the femoral artery;
locating the graft adjacent the aneurysm near
the aortic bifurcation;
25 adjusting the position of the graft relative
to the aortic aneurysm;
anchoring the proximal end of the main tubular
member in healthy tissue on one side of the aortic aneurysm;
positioning the first and second tubular members
30 in respective first and second iliac arteries;
anchoring the distal ends of the first and
second tubular members to the respective first and second iliac
arteries; and
providing a substantially fluid-tight seal at
35 each anchor point so that the graft is in fluid communication
with the vasculature and iliac arteries.

20. ~~24~~¹⁹ The method of claim ~~20~~¹⁹ further comprising the
step:

visually inspecting a plurality of radiopaque markers located on the graft by using fluoroscopic means to determine if the graft is twisted or misaligned.

21. The method of claim 20, further comprising the step:
5 realigning any twisted segments of the graft so that an unobstructed flow of fluid results.

22. A graft device having a bifurcation substantially as hereinbefore described with reference to the accompanying drawings.

10

23. A method of deploying a bifurcated graft substantially as hereinbefore described with reference to the accompanying drawings.

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DATED this 15th day of April, 1996

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EndoVascular Technologies, Inc.

By their Patent Attorneys

DAVIES COLLISON CAVE

ABSTRACT

Graft having a bifurcation for repairing an aneurysm in the vicinity of an aortic bifurcation in a patient comprising a main tubular body and first and second tubular legs joined to said main body in a bifurcation. The main body and the legs are formed of a flexible surgically implantable material. The main body and each of the first and second legs having an opening therein in communication with the other openings. Expandable spring attachments are secured to the main body adjacent the opening in the main body. An additional expandable spring attachment is secured to one of said legs adjacent the opening in said one leg.

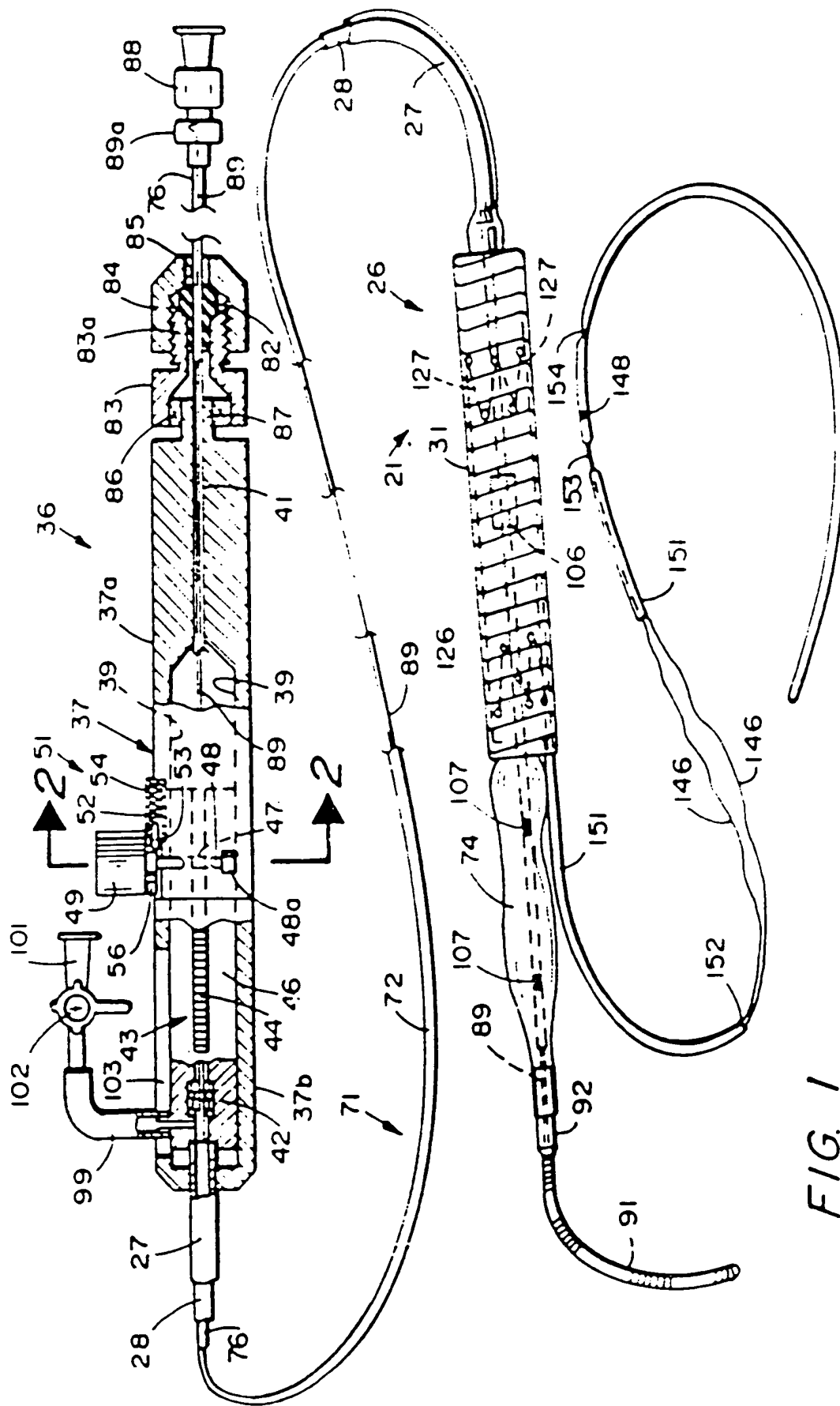


FIG. 1

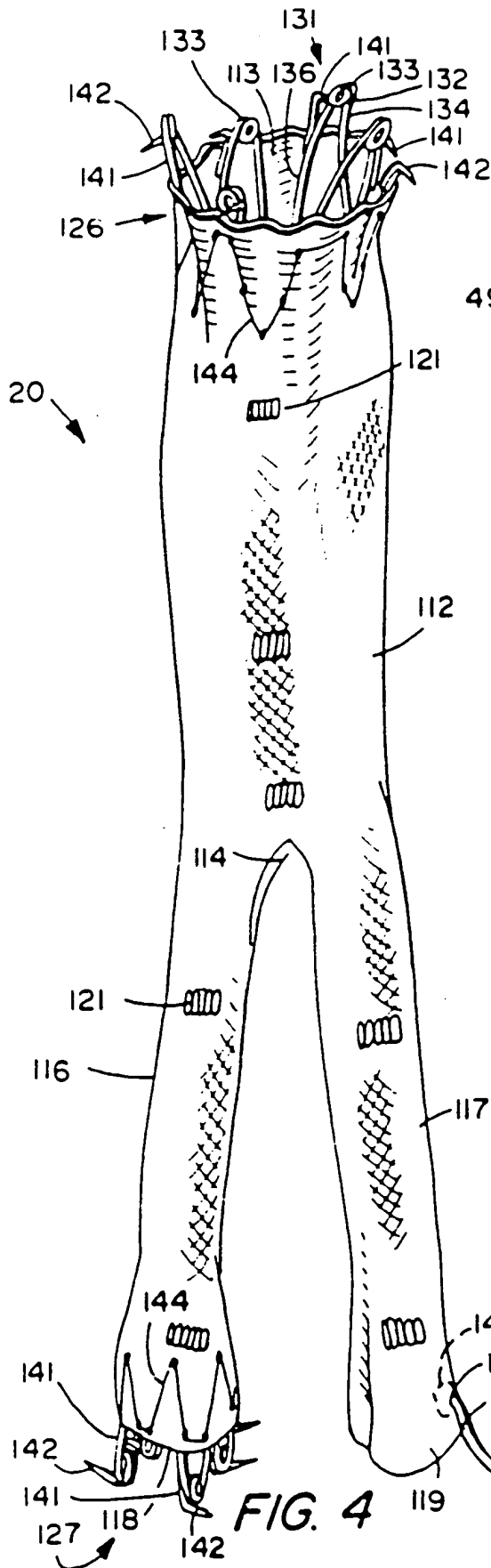


FIG. 4

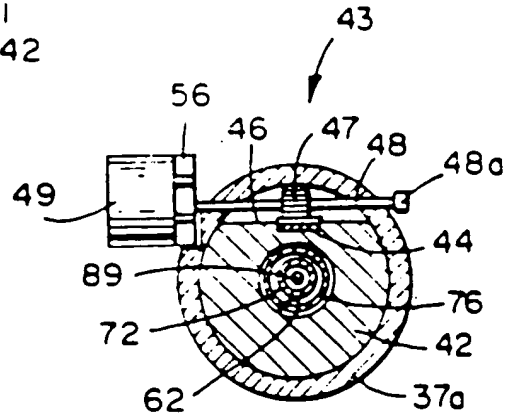


FIG. 2

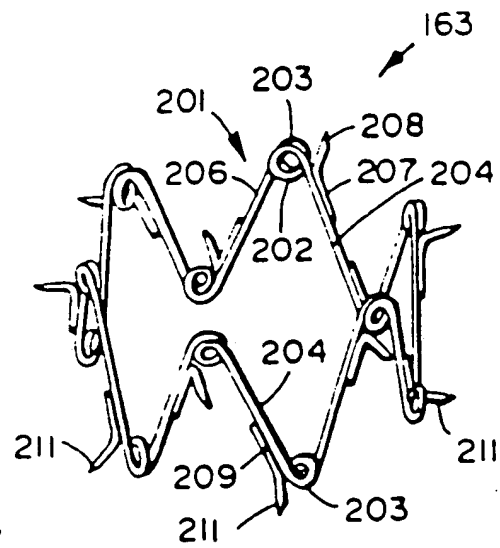
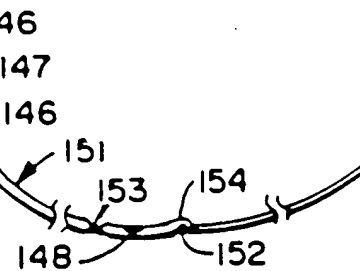


FIG. 8



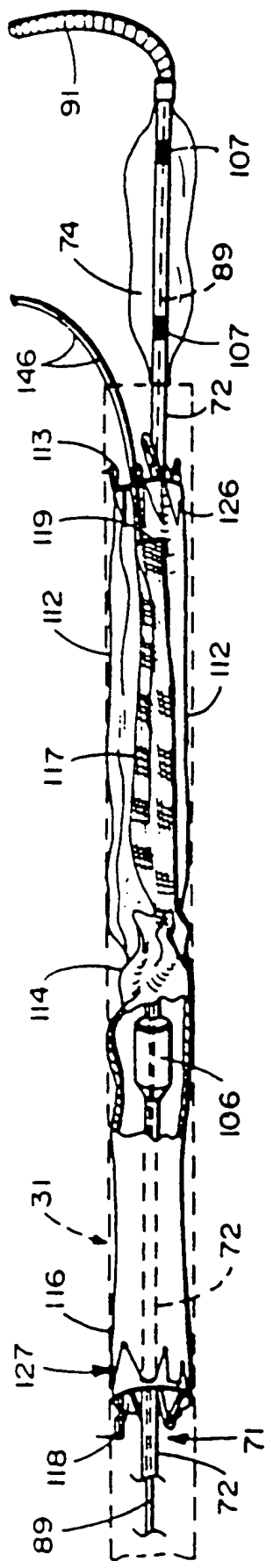


FIG. 5

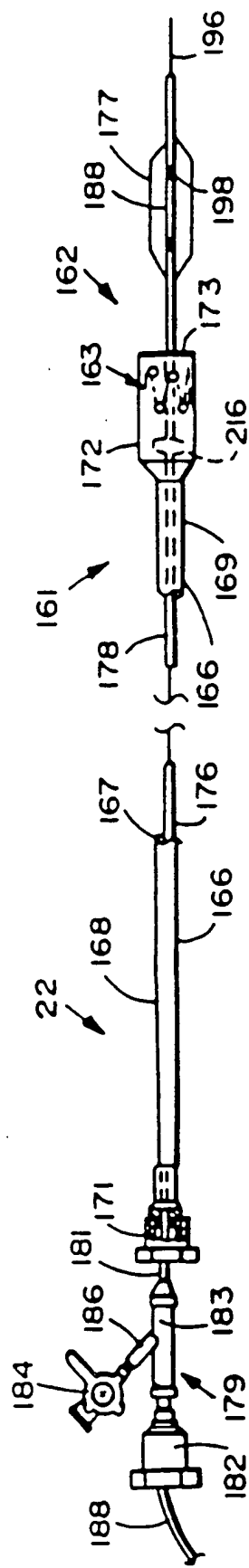


FIG. 6

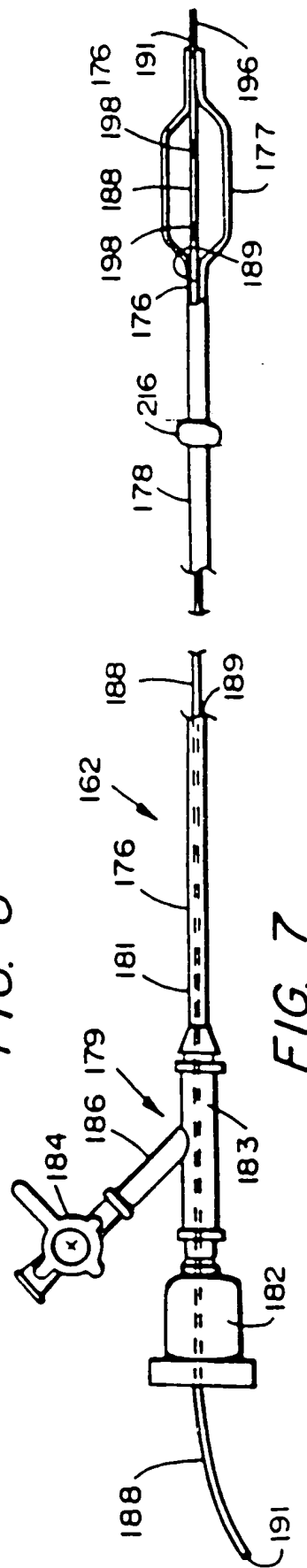


FIG. 7

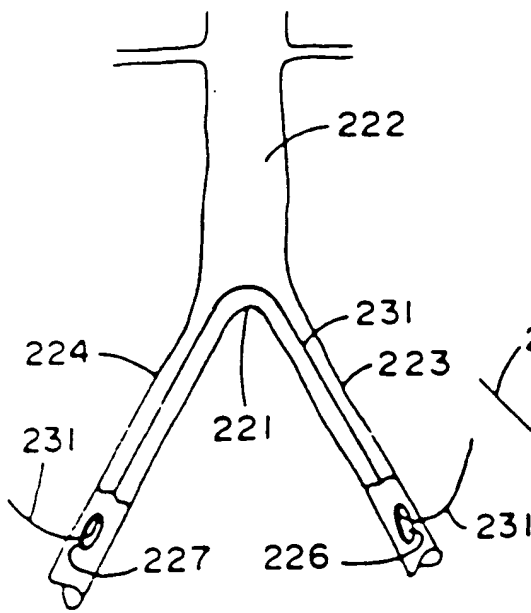


FIG. 9

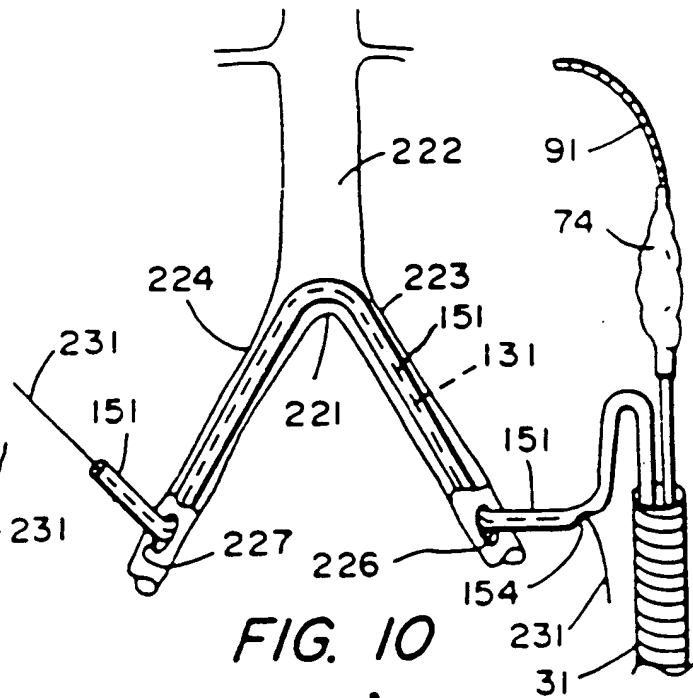


FIG. 10

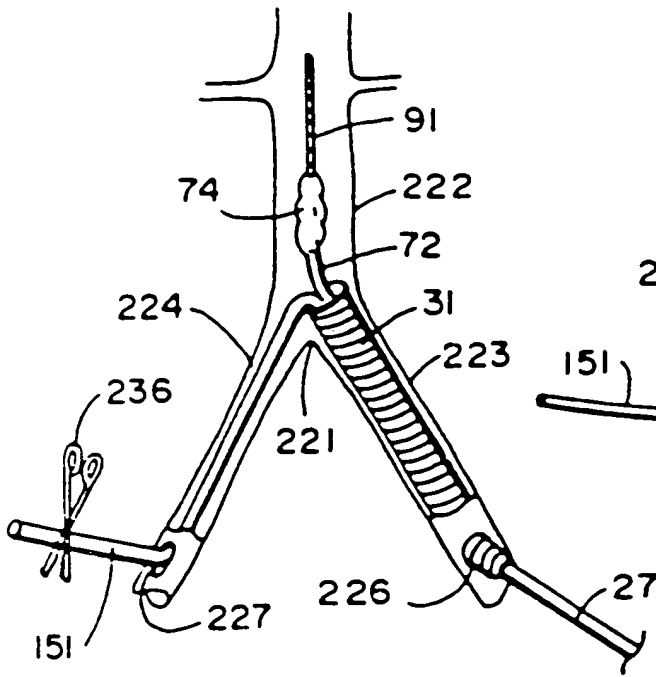


FIG. 11

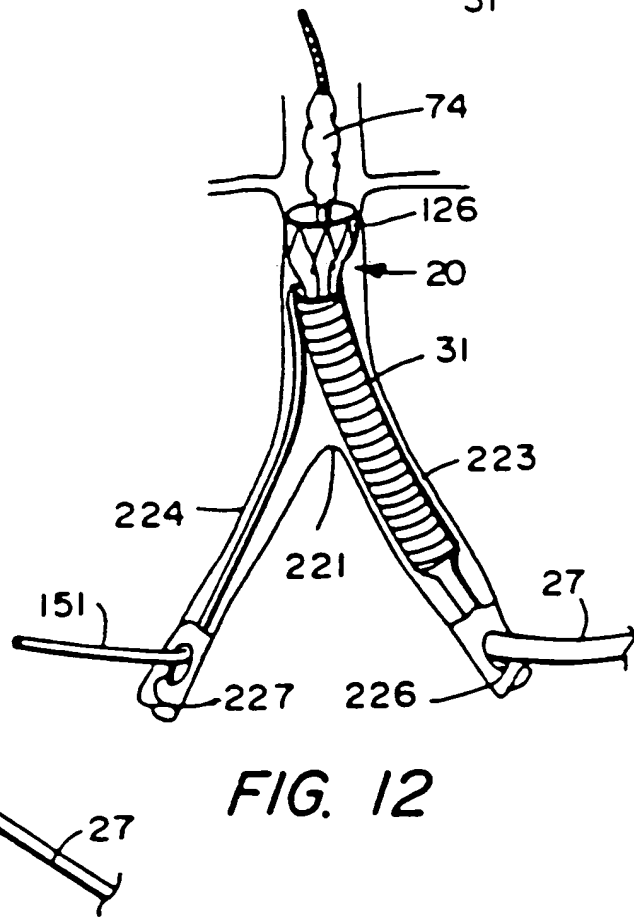


FIG. 12

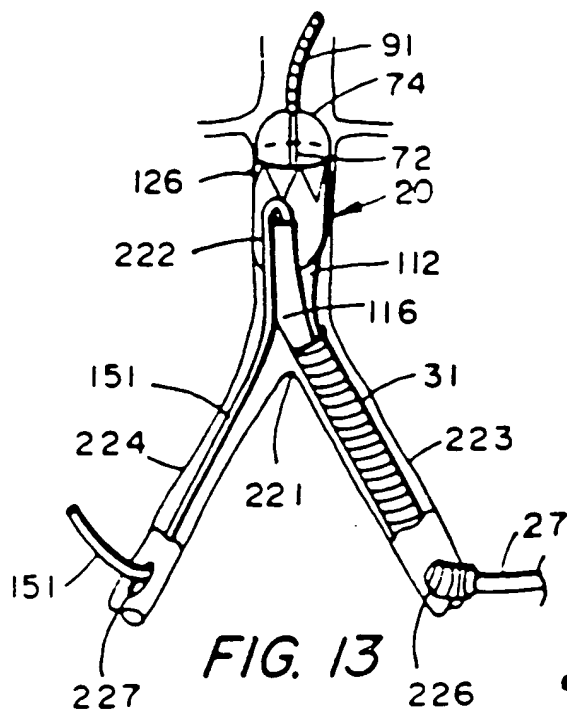


FIG. 13

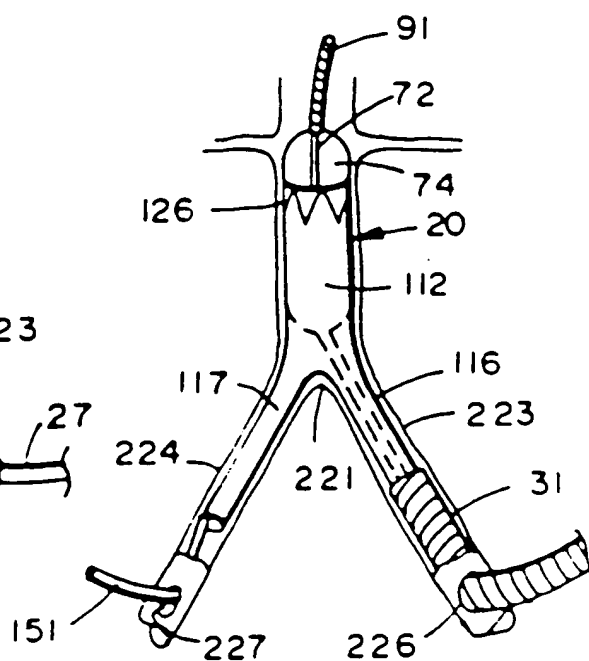


FIG. 14

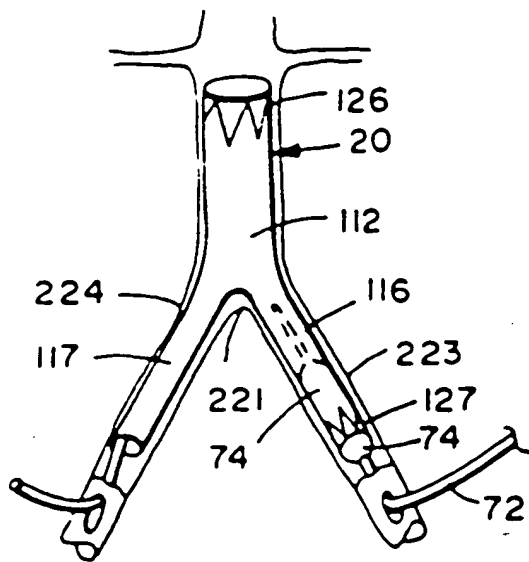


FIG. 15

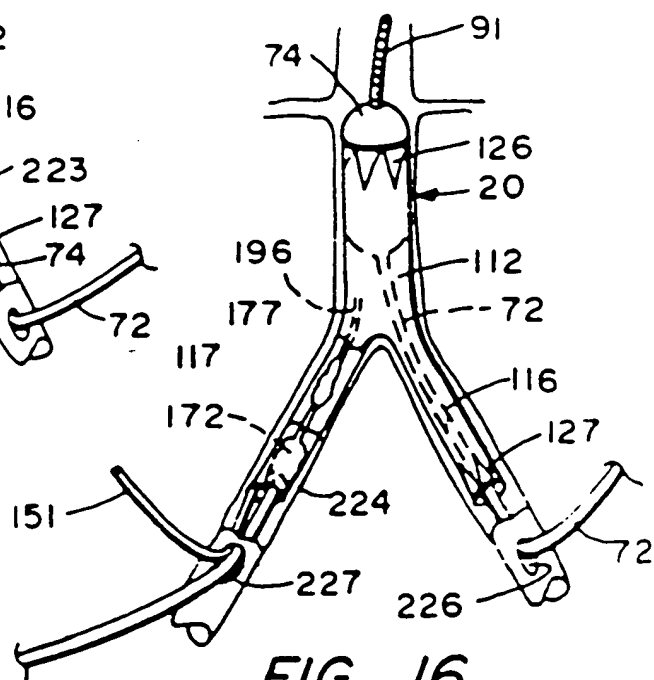


FIG. 16

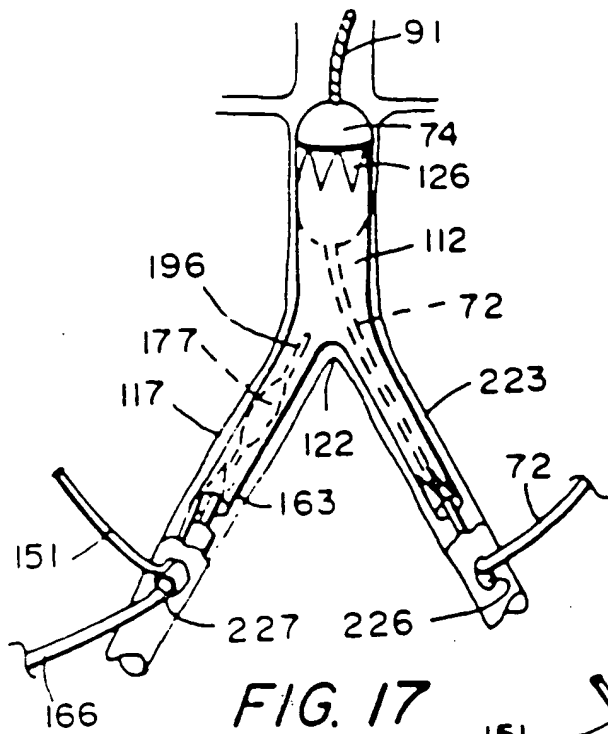


FIG. 17

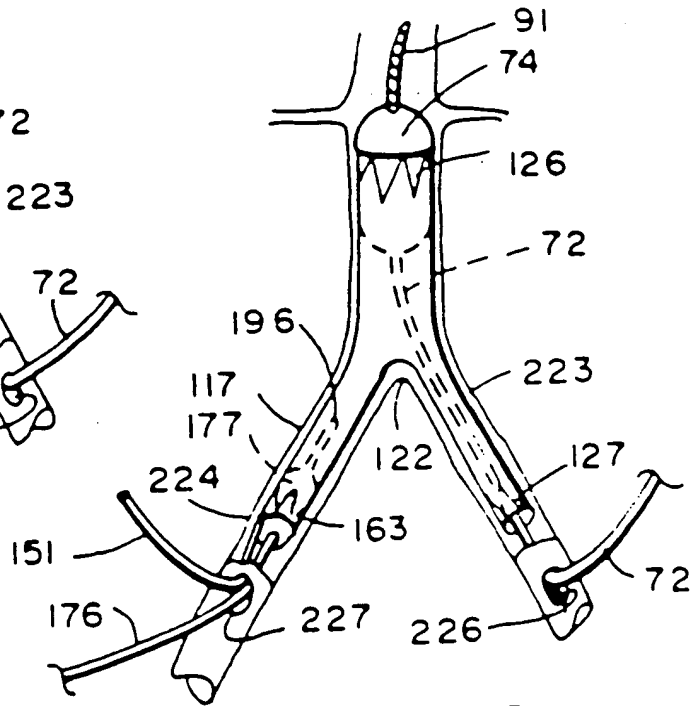


FIG. 18

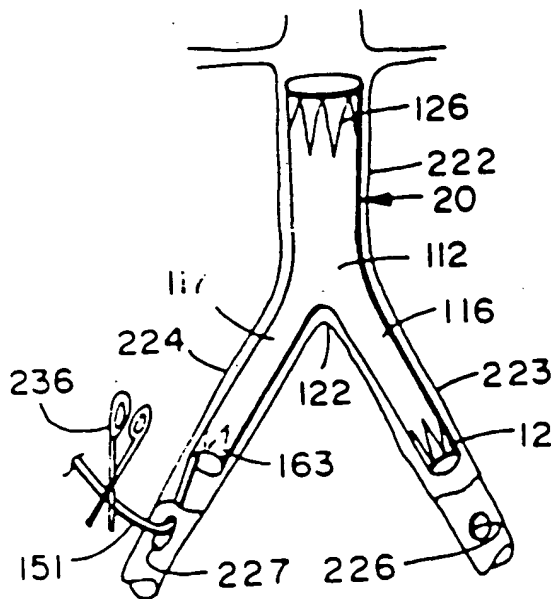


FIG. 19

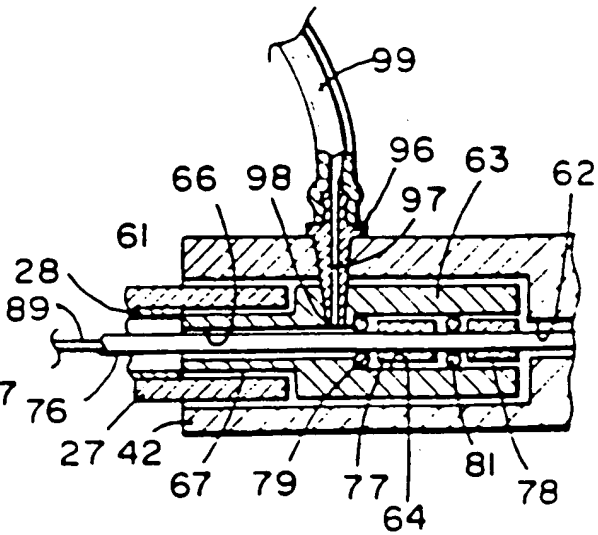


FIG. 3